Steven W. Troxler
Commissioner

North Carolina Department of Agriculture and Consumer Services

Food and Drug Protection Division

Anita MacMullan
Director

Month day, 2019

Name
Firm Name
Street Address
City, State

To whom it may concern:

It has come to our attention that (___firm name____) is (manufacturing/selling) products that contain CBD at (____ firm location_____).

Please be advised of the following regarding CBD products in the marketplace:

- It is a prohibited act under section 301(ll) of the FD&C Act [21 U.S.C. 331(ll)] to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. 355] or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.

- CBD is the active ingredient in the approved drug product Epidiolex, a drug product that has been approved under section 505 of the federal Food, Drug & Cosmetic Act ("FD&C Act"). Substantial clinical investigations have been instituted for CBD and the existence of such investigations have been made public.

- Since CBD is the active ingredient in the approved drug product Epidiolex, it is currently excluded from being a dietary supplement under section 201(ff)(3)(B)(i) and (ii) of the FD&C Act.

- CBD products marketed with claims to prevent, mitigate, diagnose, treat or cure serious diseases (aka "health claims") indicate that the products are intended for use as drugs under the FD&C Act [21 U.S.C. 321(g)(1)]. Section 201(p) of the FD&C Act [21 U.S.C. 321(p)] specifies that new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA. CBD in products other than the approved drug Epidiolex and which makes health claims would be a new drug that cannot legally be introduced into interstate commerce.

- North Carolina has routinely adopted by reference the federal Food, Drug & Cosmetic Act and implementing regulations. The violation of these federal laws and regulations would equally be a violation of state laws and regulations.

Once you place products into the marketplace, you have a responsibility to comply with all federal and state laws. Failure to comply could result in legal action being taken against you, including without limitation, embargo, seizure and injunction.

Sincerely,

Anita MacMullan
Director
Food and Drug Protection Division

cc: Joe Reardon, Assistant Commissioner for Consumer Protection
FDA/ATL-DO

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